

would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit.

(b) If unable to complete any appeals within 120 days, the institution must ask ORI for an extension in writing and provide an explanation for the request.

(c) ORI may grant requests for extension for good cause. If ORI grants an extension, it may direct the institution to file periodic progress reports.

§ 93.315 Notice to ORI of institutional findings and actions.

The institution must give ORI the following:

(a) *Investigation Report.* Include a copy of the report, all attachments, and any appeals.

(b) *Final institutional action.* State whether the institution found research misconduct, and if so, who committed the misconduct.

(c) *Findings.* State whether the institution accepts the investigation's findings.

(d) *Institutional administrative actions.* Describe any pending or completed administrative actions against the respondent.

§ 93.316 Completing the research misconduct process.

(a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues. An institution must notify ORI in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which must be reported to ORI under § 93.315.

(b) After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the institution's handling of the case and take appropriate action including:

(1) Approving or conditionally approving closure of the case;

(2) Directing the institution to complete its process;

(3) Referring the matter for further investigation by HHS; or,

(4) Taking a compliance action.

OTHER INSTITUTIONAL RESPONSIBILITIES

§ 93.317 Retention and custody of the research misconduct proceeding record.

(a) *Definition of records of research misconduct proceedings.* As used in this section, the term "records of research misconduct proceedings" includes:

(1) The records that the institution secures for the proceeding pursuant to §§ 93.305, 93.307(b) and 93.310(d), except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;

(2) The documentation of the determination of irrelevant or duplicate records;

(3) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by § 93.309(d);

(4) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to § 93.310(g); and

(5) The complete record of any institutional appeal covered by § 93.314.

(b) *Maintenance of record.* Unless custody has been transferred to HHS under paragraph (c) of this section, or ORI has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later.

(c) *Provision for HHS custody.* On request, institutions must transfer custody of or provide copies to HHS, of any institutional record relevant to a research misconduct allegation covered by this part, including the research

§ 93.318

records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS inquiry or investigation or for ORI to conduct its review or to present evidence in any proceeding under subparts D and E of this part.

§ 93.318 Notifying ORI of special circumstances.

At any time during a research misconduct proceeding, as defined in § 93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

- (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- (b) HHS resources or interests are threatened.
- (c) Research activities should be suspended.
- (d) There is reasonable indication of possible violations of civil or criminal law.
- (e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- (f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- (g) The research community or public should be informed.

§ 93.319 Institutional standards.

(a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.

(b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution's internal standards of conduct.

42 CFR Ch. I (10–13 Edition)

Subpart D—Responsibilities of the U.S. Department of Health and Human Services

GENERAL INFORMATION

§ 93.400 General statement of ORI authority.

(a) *ORI review.* ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter. The ORI response may include, but is not limited to—

- (1) Conducting allegation assessments;
- (2) Determining independently if jurisdiction exists under this part in any matter;
- (3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;
- (4) Recommending that HHS should perform an inquiry or investigation or issue findings and taking all appropriate actions in response to the inquiry, investigation, or findings;
- (5) Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions;
- (6) Reviewing an institution's findings and process;
- (7) Making a finding of research misconduct; and
- (8) Proposing administrative actions to HHS.

(b) *Requests for information.* ORI may request clarification or additional information, documentation, research records, or evidence from an institution or its members or other persons or sources to carry out ORI's review.

(c) *HHS administrative actions.* (1) In response to a research misconduct proceeding, ORI may propose administrative actions against any person to the HHS and, upon HHS approval and final action in accordance with this part, implement the actions.

(2) ORI may propose to the HHS debarbing official that a person be suspended or debarred from receiving Federal funds and may propose to other appropriate PHS components the implementation of HHS administrative